

Revision of Testing Methods for Containers and Packages Intended for Milk and Milk Products

1. Purpose and background

Containers and packages exclusively intended for milk and milk products are subject to the Ministerial Ordinances concerning Compositional Standards Etc. for Milk and Milk Products (Ministry of Health and Welfare Ordinance No. 52, 1951, herein after referred to as the “Ministerial Ordinances”), separately from containers and packages used for many other purposes.

The current testing methods for containers and packages based on the Ministerial Ordinances have been seldom modified since the initial establishment of them. These methods still contain procedures using harmful reagents, such as mercury and they do not reflect the recent advanced analytical technology. On the other hand, testing methods for containers and packages that are specified in the Specifications and Standards for Food, Food Additives, Etc. were substantially improved in 2006.

The proposed revision aims to harmonize with the testing methods in Notification No. 370 by keeping up with advanced analytical technology.

2. Outline of revision

1. Modification of testing methods

Some testing methods will be modified:

- to replace harmful reagents, such as mercury and carbon tetrachloride, by less harmful ones, and
- to improve analytical accuracy by introducing methods capable of providing higher reproducibility and other advanced methods.

The individual changes are outlined below

a. Atomic Absorption Spectrophotometry (AAS)

The use of Electrothermal-AAS will be made possible. Currently, flame-AAS is only specified as the official method. This modification will be applied to all tests using AAS as the testing methods for containers and packages specified in the Ministerial

Ordinances.

b. Material tests

Cadmium and lead

- Polarography will be removed to stop the use of mercury.
- Inductively Coupled Plasma-Atomic Emission Spectrophotometry (ICP-AES) will be added to enable multiple metals to be determined at a time.
- Hydrochloric acid treatment will be added to the preparation of the test solution to reduce the interference by barium and calcium coexisting in the solution.

Vinyl chloride and volatile matter

- The column used for gas chromatography will be changed from a packed column to a capillary column capable of providing higher determination sensitivity and separation, in order to improve resolution.

Dibutyl tin compounds

- The extracting solvent will be changed from a carbon tetrachloride-methanol mixture to an acetone-hexane mixture.
- The test by paper chromatography will be replaced by the test by GC/MS (gas chromatography/mass spectrometry) to heighten separation capability

Cresol ester phosphate

- The extracting solvent will be changed from a carbon tetrachloride-methanol mixture to acetonitrile.
- Gas Chromatography will be replaced by Liquid Chromatography to make the procedures easier and to heighten recovery and reproducibility.

c. Both material-test and migration-test categories

Arsenic

- The current method will be replaced by a new method to avoid using mercury bromide test paper.

d. Migration-test category

Antimony

- The current method will be removed and the use of AAS or ICP-AES will be made possible.

Germanium

- The current method will be removed to avoid using carbon tetrachloride.

Instead, the use of AAS or ICP-AES will be made possible.

Phenol

- The bromine method will be replaced by the 4-aminoantipyrine method to heighten detection sensitivity.

2. Indication of limit values

Limit values will be given in individual tests. In some of the current tests, including the migration tests for plastics, the determination of conformity with specification is conducted by comparing to the standard solutions specified but the corresponding limits are not given in individual tests. The proposed revision aims to let examiners know each specification limit readily. (e.g., not more than 0.8µg/ml as Pb)

3. Other matters

- Change in units: ppm → µg/ml, µg/g
- Some changes to descriptions

3. Date of enforcement

Requirements shall apply to the products manufactured or imported after the six months period beginning on the date of promulgation.